

ABC TV PHILADELPHIA

What is the current regulation for the emissions of ETO with regard to sterilization facilities?

Ethylene oxide sterilization facilities are covered under the National Emission Standards for Hazardous Air Pollutants (NESHAP) for Ethylene Oxide Commercial Sterilization and Fumigation Operations. The standards were issued in April of 2006 and are currently under review.

Proposed Rule changes for sterilizations facilities are currently under review? what are those possible changes? and what is the process of final approval and when may that happen?

EPA is in the process of reviewing the NESHAP for Ethylene Oxide Commercial Sterilization and Fumigation Operations and we expect to issue a proposed rule in 2022. The agency is currently gathering data from companies through an Information Collection Request (ICR). These data will inform the proposal and we cannot speculate on the substance of the proposal at this time. Once issued, the public will have 60 days to comment on the proposed rule, and we expect to issue a final rule in 2023.

Ex. 5 Deliberative Process (DP)

Does that include fence line monitoring? Why isn't that required? Is that a possible rule change?

We cannot speculate on the substance of the proposal regarding fenceline monitoring at this time. For current fenceline monitoring at specific facilities, you will need to check with the state.

How much ethylene Oxide is allowed to be emitted from a sterilization company? are there any proposed amounts? Do you foresee those amounts changing?

The current regulation specifies the emission reductions and limits based on the piece of equipment and the amount of ethylene oxide that the facility uses per year, not on ethylene oxide emissions ([HYPERLINK "<https://www.govinfo.gov/content/pkg/CFR-2015-title40-vol10/pdf/CFR-2015-title40-vol10-part63-subpartO.pdf>"]).

What are background ETO levels? Is that naturally occurring? What could that be from?

EPA has learned more about the health risks from breathing air that contains ethylene oxide over a lifetime, but there is a lot about ethylene oxide that we still do not know.

One of the questions we are examining is whether ethylene oxide is in the air broadly across the U.S. – and if it is, at what levels. We have a fact sheet that explains more about our work to understand background levels of EtO at: [HYPERLINK "<https://www.epa.gov/system/files/documents/2021-10/background-eto-explainer-document.pdf>"]

A proposed rule was scheduled for 2021 with regard to ETO. Has that done?

EPA issued a final rule for the Miscellaneous Organic Chemical NESHAP (MON) on August 12, 2020. More information is available here: [HYPERLINK "<https://www.epa.gov/stationary-sources-air-pollution/miscellaneous-organic-chemical-manufacturing-national-emission>"]

In addition, in June 2021, we announced that we intend to reconsider certain aspects of the 2020 air regulation "National Emission Standards for Hazardous Air Pollutants: Miscellaneous Organic Chemical Manufacturing (MON) Residual Risk and Technology Review" in response to five administrative petitions. The Agency will issue a Federal Register notice initiating public review and comment soon.